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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Cor	nplete if Known
Application Number	09/653,406
Filing Date	09/01/2000
First Named Inventor	Jennifer L. West
Group Art Unit	1615
Examiner Name	Di Nola Baron, Liliana
Attorney Docket Number	47400-0100 (47400-252658)

Examir Apitial	ای	Cite No.1	U.S. Patent	Document Kind Code ² (if known)	U.S. PATENT DOCUMENT Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevan Figures Appear
On	25	1	4,526,938		Churchill et al.	07-02-1985	
	" †	2	4,716,203		Casey et al.	12-29-1987	
-	\dashv	3	4,741,337		Smith et al.	05-03-1988	
\dashv	一	4	4,957,744		della Valle et al.	09-18-1990	
$\neg \uparrow$	\dashv	5	4,987,744		Handley et al.	01-29-1991	
\dashv	$\neg \uparrow$	6	5,410,016		Hubbell et al.	04-25-1995	
+	$\neg \dagger$	7	5,508,317		Müller	04-16-1996	
-		8	5,632,981		Saavedra et al.	05-27-1997	
+	一十	9	5,665,840		Pöhlmann et al.	09-09-1997	
$\neg \dagger$		10	5,807,927		Stockinger et al.	09-15-1998	
_		11	5,849,839		Hubbell et al.	12-15-1998	
- 1		12	5,849,841		Mühlebach et al.	12-15-1998	
		13	5,900,433		Igo et al.	05-04-1999	
		14	5,910,316		Keefer et al.	06-08-1999	
		15	5,932,674		Müller	08-03-1999	
		16	5,939,489		Müller	08-17-1999	
·—		17	6,011,077		Müller	01-04-2000	
		18	6,299,604	B1	Ragheb et al.	10-09-2001	
	1	19	6,262,206		Nesvadba et al.	07-17-2001	

				FOR	EIGN PATENT DOCUMEN	TS	- ·	
Examiner Initials	Cite No.	Office ³	Foreign Patent Doo Number ⁴	ument Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Τ ⁶
Sohes	20	PCT JO	WO 96/32136		The United States of Americaet al.	10-17-1996		
	21	PGT	WO96/15797		The United States of America represented by the Secretary, Dept. of Health and Human Services	05-30-1996		
4	22	PCT	WO 01/15738		Rice University	03-08-2001		

Examiner Signature	Lor hole Bara	Date Considered	3/17/04

'Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the weather (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the set of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁵Applicant is to place a check mark here if English language translation is attached.

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Sheet 2

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		OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS	
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	23	BOHL et al., "Nitric oxide-generating polymers reduce platelet adhesion and smooth muscle cell proliferation", Biomaterials,	
Sones		2000, 2273-2278, Vol. 21	
	24	BOHL et al., "Nitric Oxide-Releasing Materials for the Prevention of Thrombosis and Restenosis", Proceed. Int'l. Sym. Control.	1
		Rel. Bioact. Mater., 2000, 143-144, Vol. 27	
	25	BOHL et al., "Nitric Oxide Producing Materials: A Potential Therapy for Thrombosis and Restenosis", Proceed. Int'l. Sym.	
		Control. Rel. Bioact. Mater., 1999, 56-57, Vol. 26	
	26	BOHL et al., "Nitric Oxide-Releasing Hydrogels for the Prevention of Thrombosis and Restenosis", Circulation, Oct. 31, 2000;	
		II.734, Vol. 102, No. 18 (Abstract only)	
.	27	COHN et al, "Biodegradable PEO/PLA block polymers", J. Biomed. Mater. Res., 1988, 993-1009, Vol. 22	
	28	COOKE et al., "Antiatherogenic Effects of L-Arginine in the Hypercholesterolemic Rabbit", J. Clin. Invest., 1992, 1168-1172,	
		Vol. 90	į
	29	DE GRAAF et al., "Nitric Oxide Functions as an Inhibitor of Platelet Adhesion Under Flow Conditions", Circulation, 1992, 2284-	
-		2290, Vol. 85	
	30	DE MEYER et al., "Effect of Nitric Oxide Donors on Neointima Formation and Vascular Reactivity in the Collared Carotid Artery	
		of Rabbits", J. Cardiovasc. Res., 1995, 272-279, Vol. 26	
	31	DIODATI et al., "Complexes of Nitric Oxide with Nucleophiles as Agents for the Controlled Biological Release of Nitric Oxide:	
		Hemodynamic Effect in the Rabbit", J. Cardiovasc. Pharm., 1993, 287-292, Vol. 22	
	32	DIODATI et al., "Complexes of Nitric Oxide with Nucleophlles as Agents for the Controlled Biological Release of Nitric Oxide:	
		Antiplatelet Effect*, Throm. Haem., 1993, 654-658, 1993	
	33	GARG et al., "Nitric Oxide-Generating Vasodilators and 8-Bromo Cyclic Guanosine Monophosphate Inhibit Mitogenesis and	
		Proliferation of Cultured Rat Vascular Smooth Muscle Cells", J. Clin. Invest., 1989, 1774-1777, Vol. 83	
1	34	GREENHALGH, "The Role of Growth Factors in Wound Healing", J. Trauma, 1996, 159-167, Vol. 41	
	35	HELLER et al., "Nitric Oxide Inhibits Proliferation of Human Endothelial Cells via a Mechanism Independent of cGMP".	
		Atherosclerosis, 1999, 49-57, Vol. 144	
1	36	HERN et al., "Incorporation of Adhesion Peptides into Nonadhesive Hydrogels Useful for Tissue Resurfacing", J. Biomed.	
4		Mater. Res., 1998, 266-276, Vol. 39	

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Examiner Signature	Ler nole Baro	Date 3/17/04	RECEIVED

¹Unique citation designation number. ²Applicant is to place a check mark here if English language translation is attached.

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Application Number 09/653,406			
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0	37	HOLLAND et al., "Polymers for Biodegradable Medical Devices. 1. The Potential of Polyesters as Controlled Macromolecular	
Lenes		Release Systems, 1986, 155-180, Vol. 4	
	38	IGNARRO et al., "Mechanism of Vascular Smooth Muscle Relaxation by Organic Nitrates, Nitroprusside and Nitric	
		Oxide: Evidence for the Involvement of S-Nitrosothiols as Active Intermediates*, J. Pharmacol. Exp. Ther., 1981, 739-749, Vol.	
		218	
	39	KWON et al., "Inhibition of Tumor Cell Ribonucleotide Reductase by Macrophage-derived Nitric Oxide", J. Exp. Med., 1991,	
		761-767, Vol. 174	ļ
	40	LEFER et al., "Antineutrophil and Myocardial Protecting Actions of a Novel Nitric Oxide Donor After Acute Myocardial Ischemia	
		and Reperfusion in Dogs", Circulation, 1993, 2337-2350, Vol. 88	
_ _	41	LEGRAND et al., "Preclinical Promise of Becaplermin (rhPDGF-BB) in Wound Healing", Am. J. Surg., 1998, 48S-54S, Vol 176	
•	42	LEPOIVRE et al., "Inactivation of Ribonucleotide Reductase by Nitric Oxide", Biochem. Biophys. Res. Comm., 1991, 442-448,	
		Vol. 179	
	43	MANN et al., "Tethered-TGF-β Increases Extracellular Matrix Production of Vascular Smooth Muscle Cells", Biomaterials,	
		2001, 439-444, Vol. 22	
	44	MARAGOS et al., "Nitric Oxide/Nucleophile Complexes Inhibit the in Vitro Proliferation of A375 Melanoma Cells via Nitric	
		Oxide Release", Cancer Res., 1993, 564-568, Vol. 53	
	45	MARTINEZ-DE JESUS et al., "Randomized Single-Blind Trial of Topical Ketanserin for Healing Acceleration of Diabetic Foot	
i		Ulcers", Arch. Med. Res., 1997, 95-99, Vol. Spring 28 (1) (Abstract only)	<u> </u>
	46	MATHEWS et al., "Biological Activity of S-Nitrosothiols: The Role of Nitric Oxide", J. Pharmacol. Exp. Therap., 1993, 1529-	
		1537, Vol. 267	
	47	MORO et al., "cGMP Mediates the Vascular and Platelet Actions of Nitric Oxide: Confirmation Using an Inhibitor of the Soluble	
		Guanylyl Cyclase*, Proc. Natl. Acad. Sci. USA, 1996, 1480-1485, Vol. 93	
	48	RODOMSKI et al., "Comparative Pharmacology of Endothelium-Derived Relaxing Factor, Nitric Oxide and Prostacyclin in	
		Platelets", Br. J. Pharmacol., 1987, 181-187, Vol. 92	
	49	SARKAR et al., "Nitric Oxide Inhibition of Endothelial Cell Mitogenesis and Proliferation", Surgery, 1995, 274-279, Vol. 118	
I	1		

La nole Bara RECEIVED Examiner Signature Considered

Substitute for Form 1449/A/PTO **Application Number** 09/653,406 Filing Date 09/01/2000 INFORMATION DISCLOSURE First Named Inventor Jennifer L. West STATEMENT BY APPLICANT Group Art Unit 1615 Di Nola Baron, Liliana Examiner Name (use as many sheets as necessary 47400-0100 (47400-252658) Attorney Docket Number Sheet 4 of 4 OTHER INFORMATION - NON PATENT LITERATURE DOCUMENTS SAWHNEY et al., "Rapidly Degraded Terpolymers of dl-Lactide, Glycolide, and ε-Caprolactone with Increased Hydrophilicity 50 by Copolymerization with Polyethers", J. Biomed. Res., 1990, 1397-1411, Vol. 24 Sono SCOTT-BURDEN et al., "Extracellular Matrix: Differential Influence on Growth and Biosynthesis Patterns of Vascular Smooth Muscle Cells from SHR and WKY Rats", J. Cell Physiol., 1989, 267-274, Vol. 141 SCOTT-BURDEN et al., "Genetically Engineered Smooth Muscle Cells as Linings to Improve the Biocompatibility of 52 Cardiovascular Prostheses", Circulation, 1996, Il235-238, Vol. 94 (9 Suppl.) SMITH et al., "Nitric Oxide-Releasing Polymers Containing the [N(O)NO] Group", J. Med. Chem., 1996, 1148-1156, Vol. 39 53 SPILIZEWSKI et al., "The Effect of Hydrocortisone Acetate Loaded Poly (DL-Lactide) Films on the Inflammatory Response", J. 54 Control, Rel., 1985, 197-203, Vol. 2 STUEHR et al., "Nitric Oxide - A Macrophage Product Responsible for Cytostasis and Respiratory Inhibition in Tumor Target 55 Cells", J. Exp. Med., 1989, 1543-1555, Vol. 169 WILLIAMS et al., 'Safety and Tolerability of Intravenous-to-Oral Treatment and Single-Dose Intravenous or Oral Prophylaxis 56 with Trovafloxacin", Am. J. Surg., 1998, 745-79S, Vol. 176 WIEMAN et al., "Efficacy and Safety of a Topical Gel Formulation of Recombinant Human Platelet-Derived Growth Factor-BB 57 (Becaplermin) in Patients with Chronic Neuropathic Diabetic Ulcers", Diabetes Care, 1998, 822-827, Vol. 21 ZICHE et al., "Nitric Oxide Promotes DNA Synthesis and Cyclic GMP Formation in Endothelial Cells from Postcapillary 58 Venules", Biochem. Biophys. Res. Comm., 1993, 1198-1203, Vol. 192 Abstract, Derwent WPI, HU 9801673 A1 (08-28-2000), (Cycl-N) Cyclolab Ciklodextrin Kutato Fejleszto, 59

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